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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,998	03/30/2004	Edward J. Ellis	VIS-0008-P2	6070

23413 7590 10/06/2006

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,998	ELLIS	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/05,10/05,*₿03/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-12 and 17-23, as drawn to any species of a glycoprotein, in the reply filed on 08/23/2006 is acknowledged. Claims 3-10, and 13-16 are withdrawn as being drawn to non-elected subject matter. Claims 1-12 and 17-23 are examined on the merits as drawn to any species of a glycoprotein (Applicant was telephoned to elect a specific glycoprotein, as required by restriction, but no return call was ever received).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 17-23 are rejected under 35 U.S.C. 103(a) as being obvious over any of Kaufman (US 4,923,699), Leahy I et al. (US 6,281,192 B1) or Leahy II et al. (US 6,429,194 B1) (collectively discussed under Leahy I et al.) in view of Ogawa et al. (US 5,830913).

Kaufman teaches an ophthalmic preparation comprising a glycoprotein (mucin) for e.g. dry eye, that is inherently derived from whey, is inherently autoclavable (the latter two inherency's evidenced by the Leahy et al. references below), includes a buffering agent such as a carrier, and may be used in a container (col. 10, line 60-68; col. 11).

Leahy I and II et al. teach an ophthalmic preparation comprising a glycoprotein (e.g. mucin) for the treatment of dry eye (col. 1, line 57; claim 25), which may be derived from dairy

whey (col. 7, line 32; claim 16), is autoclavable (claim 21), and further comprises an option for any of viscosifiers, buffering agents, tonicity agents, humectants, wetting agents, or other therapeutic drugs (col. 8, claims 10-15).

The references teach the use of known glycoproteins. Since it is not known it they are also referred to as glycomacroproteins (or capable of the latter, depending on the isolated form or preference, or how the latter is defined, see 112 2nd rejection); the claims have nevertheless been rejected under 103 (as opposed to 102). However, the references do not expressly teach a therapeutic package, with the specific labeling or specific amounts of administration in the form of %'s or "ml" (as opposed to percents of compounds therein) (Applicant's claims 17-23). . [It is noted that the forms form which the glycomacroproteins may be derived (dairy whey, casein, sweet whey, purified whey, e.g. claims 2-3, and 11-12), as well as the Dalton size are deemed inherent properties of such glycoproteins/macroproteins, absent evidence to the contrary.]

Ogawa et al. (merely cited by example in the art of known kits/products/labels for such preparations) teach an ophthalmic preparation for the treatment of dry eye comprising a container and labeling (title, col. 3, lines 35-57; col. 7, lines 24-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate an ophthalmic preparation comprising a glyco*macro*protein (if not inherent therein), as opposed to merely a glycoprotein, within packages with labels directed to specific patients likely to use the same, and specific amounts thereof in the form of "ml" in any of Kaufman, or Leahy I or II et al, because Ogawa et al. advantageously teach dry eye formulations within packages/containers with instructive labeling, and the selection of "ml" as opposed to %'s for the directed amount of use is merely a matter of routine optimization by

pharmacist in the dry eye field, depending on the choice of amount labeling (e.g. percents therein or "ml" of the active compound).

Claims 1, 4-10, and 17-23 are rejected under 35 U.S.C. 103(a) as being obvious over Hayashi (US 5,145,680) in view of Ogawa et al. (US 5,830913).

Hayashi teaches an ophthalmic preparation comprising a glycoprotein (Vitronectin), that is autoclavable, and may further comprise e.g. a buffer, (col. 1, line 42; claim 2; col. 2, line 18). Hayashi teach the use of a known glycoprotein. Since it is not known it the glycoprotein in Hayashi is also referred to as glycomacroproteins (or capable of the latter, depending on the isolated form or preference, or how the latter is defined, see 112 2nd rejection); the claims have nevertheless been rejected under 103 (as opposed to 102). However, the reference does not expressly teach a therapeutic package, with the specific labeling or specific amounts of administration in the form of %'s or "ml" (as opposed to percents of compounds therein) (Applicant's claims 17-23). [It is noted that the forms form which the glycomacroproteins may be derived (dairy whey, casein, sweet whey, purified whey, e.g. claims 2-3, and 11-12), as well as the Dalton size are deemed inherent properties of such glycoproteins/macroproteins, absent evidence to the contrary.] [It is also noted that Hayashi does not teach or render obvious claim 2, as the glycoprotein therein, is not isolated from dairy whey, casein, sweet whey, or purified whey, but rather from serum].

Ogawa et al. (merely cited by example in the art of known kits/products/labels for such preparations) teach an ophthalmic preparation for the treatment of dry eye comprising a container and labeling (title, col. 3, lines 35-57; col. 7, lines 24-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate an ophthalmic preparation comprising a glycoprotein, within packages with labels directed to specific patients likely to use the same, and specific amounts thereof in the form of "ml" in Hayashi, because Ogawa et al. advantageously teach dry eye formulations within packages/containers with instructive labeling, and the selection of "ml" as opposed to %'s for the directed amount of use is merely a matter of routine optimization by pharmacist in the dry eye field, depending on the choice of amount labeling (e.g. percents therein or "ml" of the active compound).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

The applied references under Leahy I and Leahy II have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration

under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,281,192 B1 and claims 1-21 of U.S. Patent No. 6,429,194 B1 (collectively discussed under Leahy I et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because

although neither expressly refer to mucin as a glycopeptide (which it is), both the '192 and '194 patents both teach an ophthalmic preparation comprising a glycoprotein (e.g. mucin) (and obvious to use a glycomacroprotein of the same, if not inherent therein) for the treatment of dry eye (claim 25), which may be derived from e.g. dairy whey (claim 16) or other known milk products, etc., is autoclavable (claim 21), and further comprises an option for any of viscosifiers, buffering agents, tonicity agents, humectants, wetting agents, or other therapeutic drugs (claims 10-15).

Claims 1-12 and 17-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 11-12, and 19-26 of copending Application No. US 10/814,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only minor differences of the claims of '001 are that the glycomacroproteins are claimed as glycoproteins (which are deemed to be the same or merely smaller versions of the same proteins useable in the invention), and there is an option for the protein to be derived from dairy whey (or obvious from some other form of milk byproduct, like dairy whey), and the variation in form of amount claiming (e.g. %'s herein), is deemed a mere obvious alternative form, absent evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In e.g. claim 1, it is not understood what the meant by the term glycomacroprotein, as opposed to merely glycoprotein. Namely, it was not found in the specification where the clear distinction lies, and thus, whether the former is not naturally isolated (like mucin, a known glycopeptide) or has to be synthetically altered?

Claims 20 and 22 are directed to a glycoprotein that is "substantially free" of: lactoferrin; immunoglobulin; beta-lactoblobulin; alpha-lactalbumin; and bovine serum albumin". The specification was not found to lend any guidance as to what "substantially free" means. Therefore, a reasonable interpretation of the claim language, indicates that the glycoproteins still contain some degree of one or more of these compounds, and the art is deemed to read thereon, absent evidence to the contrary.

Claim Observation

In claim 4, it is believed the term "Dalton" is to be capitalized, in proper form.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 09/30/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654